MAR 7 - 2005

K050175 pg 1 of 2

SPECIAL 510(k) SUMMARY
for the INION OTPS™ Biodegradable Pin / device modification

MANUFACTURER
Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere

Contact Person
Hanna Marttila
Regulatory Affairs Director
Lääkärinkatu 2
FIN-33520 Tampere
Phone: +358 3 2306 600
Fax: +358 3 2306 691
Hanna.Marttila@Inion.fi

DEVICE NAME
Trade name: Inion OTPS™ Biodegradable Pin
Common/Usual Name: Pin, Fixation

ESTABLISHMENT REGISTRATION NUMBER
9710629

DEVICE CLASSIFICATION AND PRODUCT CODE
Classification Panel: Orthopedic
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY

PREDICATE DEVICE
Inion OTPS™ Biodegradable Pin (K031712)

CONFORMANCE WITH PERFORMANCE STANDARDS
No applicable mandatory performance standards exist for this device.

THE REASON FOR Special 510(k)

Currently the Inion OTPS™ Biodegradable Pins are manufactured by extrusion followed by grinding and cutting. This special 510(k) is submitted to additional manufacturing method by injection moulding followed by cutting.

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Previously 510(k) cleared Inion OTPS™ Biodegradable Pin (K031712) is manufactured by extrusion followed by grinding and cutting. With this special 510(k) we inform for additional manufacturing method by injection moulding followed by cutting. Injection moulded Inion OTPS™ Biodegradable Pins are identical in all the other aspects with the predicate pins except this manufacturing method. Material recipe with copolymer composition is identical. Only difference is that the molecular weight is slightly higher with the extrusion recipe than with the injection moulding recipe.

EQUIVALENCE TO MARKETED PRODUCTS

Injection moulded Inion OTPS™ Biodegradable Pins are essentially identical with the previously 510(k) cleared extruded/machined Pins. Raw material composition with the both devices is identical except slightly lower molecular weight with the injection moulding recipe when compared to the extrusion/machining recipe. Degradation by-products are biocompatible, with no short - or long-term safety concerns. There are no new risks associated with use of the injection moulded Inion OTPS™ Biodegradable Pins as compared to the predicate device.

Injection moulded Inion OTPS™ Biodegradable Pins are substantially equivalent to predicate device used in maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts as shown by the verification testing and do not raise any new questions on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 - 2005

Ms. Hanna Marttila
Director, Regulatory Affairs
Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere
Finland

Re: K050275
Trade/Device Name: Inion OTPS™ Biodegradable Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: February 3, 2005
Received: February 7, 2005

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Inion Ltd.
510(k) Number: K050275
Device Name: Inion OTPS™ Biodegradable Pin

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Contraindications:

The Inion OTPS™ Biodegradable Pin should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse).

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050275